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Achieving an Optimal Childhood Vaccine Policy

Douglas J. Opel, MD, MPH; Jason L. Schwartz, PhD; Saad B. Omer, MBBS, PhD; Ross Silverman, JD, MPH; Jeff Duchin, MD; Eric Kodish, MD; Douglas S. Diekema, MD, MPH; Edgar K. Marcuse, MD, MPH; Walt Orenstein, MD

Policies to remove parents' ability to opt-out from school immunization requirements on the basis of religious or personal beliefs (ie, nonmedical exemptions) may be a useful strategy to increase immunization rates and prevent outbreaks of vaccine-preventable disease. However, there is uncertainty about the effectiveness of this strategy and the range of possible outcomes. We advocate for a more deliberative process through which a broad range of outcomes is scrutinized and the balance of values underlying the policy decision to eliminate nonmedical exemptions is clearly articulated. We identify 3 outcomes that require particular consideration before policies to eliminate nonmedical exemptions are implemented widely and outline a process for making the values underlying such policies more explicit.

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Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Douglas J. Opel, MD, MPH, Treuman Katz Center for Pediatric Bioethics, Seattle Children's Research Institute, 1900 Ninth Ave, M/S: JMB-6, Seattle, WA 98101 (douglas.opel@seattlechildrens.org).

After a decades-long surge in vaccine hesitancy, a multistate measles outbreak in 2015, and continuing controversy related to vaccination requirements for school and child-care entry, childhood vaccine policy in the United States may be at a tipping point. In 2015, California became the first state in more than 35 years to remove nonmedical exemptions (NMEs) based on religious or philosophical beliefs from its school immunization law, joining West Virginia and Mississippi as the 3 states to permit only medical exemptions.[1,2] In August 2016, the American Academy of Pediatrics became the third prominent professional medical organization (after the Infectious Diseases Society of America and the American Medical Association) to call on the remaining 47 states to eliminate NMEs.[3]

The basis for the recent pivot away from NMEs rests in the epidemiologic, ethical, and legal foundations of school immunization laws. School immunization laws are effective at decreasing disease incidence by increasing vaccination coverage.[4] In addition, those who obtain NMEs are at higher risk of developing and transmitting vaccine-preventable disease (VPD) to others,[5] some of whom have conditions that contraindicate their receipt of some required vaccines. Eliminating NMEs can thus help to prevent community outbreaks and protect vulnerable children and adults while also reducing the fairness problem posed by free-riders: individuals who refuse vaccination to avoid the risks (however minor) of vaccines yet still receive the benefits of community immunity. Courts have consistently upheld the constitutionality of laws that require children to be vaccinated to attend school,[1] citing the state's authority to protect the public from the harm of VPDs as sufficient justification for imposing burdens on individual choice concerning vaccination.

Despite these justifications for eliminating NMEs, apprehension regarding this strategy exists.[6] Since the 1960s, legislators have acceded to public sentiment and included religious exemptions in school immunization laws. The primary rationale for striking this balance between the state's responsibilities to protect children (and through them, the community) from serious VPDs and to respect strongly held individual beliefs has been to reduce perceptions of coercion and enhance the acceptability and sustainability of school immunization laws.[7] This ultimately has been successful: the national median vaccination coverage level of kindergarten children remains high (nearly 95% for measles-mumps-rubella [MMR], diphtheria-tetanus-acellular pertussis, and varicella vaccines) and the median exemption rate remains low (<2%).[8] Although these data mask significant local variability in coverage and exemption rates, they may nonetheless generate the perception that eliminating NMEs broadly is unnecessarily coercive. This, in turn, could "fuel public opposition" to vaccination activities.[9(p1100)] Indeed, despite California's legislative success, several other states in recent years have also tried to eliminate NMEs but failed, in part due to public opposition.

Underlying the apprehension to eliminate NMEs is an uncertainty about the relative likelihood of potential outcomes. Will there be a rise in the number of parents who home-school their children or seek clinicians willing to provide medical exemptions upon request even when no medical contraindications exist, thereby undermining the strategy's effectiveness?[1] Or will eliminating NMEs enhance conformity regarding vaccination, resulting in higher sustained coverage levels?[10] Since California's legislation is the first of its kind in decades and is only now being implemented, we will not know its net beneficial and/or unintended effects on vaccine coverage or resistance for some time, and there is little precedent available to help predict these outcomes.

There is also uncertainty regarding the breadth of potential outcomes. To date, policymakers have focused on a relatively narrow range of effects and have not yet established a systematic process for identifying, characterizing, and evaluating potential outcomes associated with a policy to eliminate NMEs.[3] However, responsible policymaking requires not only anticipating outcomes, but may also require incorporating measures to proactively mitigate adverse outcomes. The recent rhetoric that appears intent on resurrecting debunked vaccine myths serves as a portentous reminder.[11-13]

To this end, before the elimination of NMEs becomes widely adopted, we support a broad assessment of the range of possible outcomes that could follow NME elimination and urge consideration of 3 outcomes as a start: enforcement, vaccine confidence, and policy precedent. We also advocate for more open, inclusive, and expansive discussions regarding the values underlying the policy decision to eliminate NMEs. By taking these positions, we are not questioning the safety or effectiveness of childhood vaccines. Nor is it our intent to deviate from the shared goal to have as many children immunized as possible. Rather, we believe further deliberation, scrutiny, and transparency about policies to eliminate NMEs is warranted to not only help determine whether eliminating NMEs is the optimal policy approach, but to also help ensure the success of such policies in maintaining the broad consensus that has long supported childhood vaccination.

Enforcement

One potential concern with the advent of policies that eliminate NMEs is that enforcement may become the public face of immunization policy. Enforcement of school immunization laws by school districts and health departments has been a long-standing challenge due to resource constraints. As a result, compliance is usually incomplete. In some states, such as Vermont and Washington during the 2014-2015 school year, the proportion of kindergarteners out of compliance with vaccination requirements (ie, whose parents have neither sought an exemption nor submitted evidence that their children are immunized) exceeded the proportion whose parents claimed exemptions.[14,15]

Currently, enforcement of school immunization laws is typically most visible in response to an outbreak of VPD when the threat of disease is widely perceived as imminent. To achieve the policy goals of NME elimination, however, local schools and health departments would need to augment their procedures—and receive additional resources from governments to do so—to ensure compliance despite parental objections and often without a perceived threat of VPD locally. How these transformations would affect public support of vaccination that has contributed to the success of school and child care immunization laws warrants careful consideration, especially since the public's view of the appropriateness of the strategy to eliminate NMEs is uncertain. In one survey, for instance, 41% of parents support excluding a child who is not up-to-date on vaccines from child care until all vaccines are received.[16] But in other surveys, 30% of US adults think that parents should be able to decide not to vaccinate their child[17] and 17% think parents should be able to decide not to vaccinate their child specifically with MMR vaccine, even if doing so might create health risks for others.[18]

Vaccine Confidence

Public acceptance of school immunization laws that do not allow NMEs will require a high level of confidence in the safety of required vaccines. Although most parents believe vaccines are safe, vaccine safety concerns remain common.[19] These safety concerns may be heightened by taking away parents' ability to opt-out, as lack of control is an important factor influencing risk perception.[20] Currently, our ability to assess and improve vaccine confidence is limited.[21] Therefore, in conjunction with broadly implementing a policy to eliminate NMEs, it may be important to devote more resources and attention to improving vaccine confidence by addressing parents' vaccine safety concerns.

In addition, the person best positioned to address parental vaccine safety concerns is the child's health care clinician. Parents routinely cite their child's clinician as the most influential factor in their vaccine decision making, and information and reassurance about vaccines has been shown to influence parents who were planning to delay or refuse vaccines to change their mind.[22] The time needed to provide vaccine counseling to parents who have vaccine safety concerns, however, is both scarce during the already crowded health supervision visit and not reimbursed. Improving reimbursement for counseling of vaccine-hesitant parents could be an important adjunct to a policy that eliminates NMEs.

Policy Precedent

Immunization policy can influence other public health policies. For example, the principles delineated in *Jacobson vs Massachusetts*, the landmark 1905 US Supreme Court decision upholding the right of a Massachusetts city to mandate vaccination, support many uses of authority to protect the public's health, such as quarantine imposed for communicable diseases, tobacco control efforts, product regulation, and reporting requirements for sexually transmitted infections.[23] Therefore, eliminating NMEs should prompt deliberation about the policy precedent that this strategy could set for other public health contexts.

One policy precedent may be that the elimination of NMEs is interpreted as lowering the level of threat needed to justify restricting civil liberties for public health. In general, the restriction of civil liberties needs to be reasonable based on both the scope and nature of the public health threat and the degree of infringement on individual rights.[24] There also must be a direct relationship between the restriction of liberty and the reduction of the threat. To date, policies that eliminate NMEs apply to all vaccines included in school immunization laws, even though those laws include vaccines that protect against VPDs that differ (considerably, for many) in their likelihood of spreading in a school setting and the nature and scope of the immediate threat that they pose to public health. For instance, some vaccines included in school immunization laws (eg, the MMR vaccine) protect against highly infectious agents (eg, measles) that are easily spread in the school setting where they represent an acute threat to public health. Other required vaccines, such as hepatitis B, do not have these features; rather, they help to attain a more recent and broader policy goal of school immunization laws to reach a population health goal of inducing both individual and community protection against adverse outcomes from VPDs usually acquired in the postschool setting.[25] The justification for restricting liberty may be more compelling for some vaccines (eg, MMR) than others (eg, hepatitis B) because they address school-based transmission.[26]

Modern legal and ethical norms demand close scrutiny of any use of sovereign authority that negatively affects personal liberty. Leaders in public health ethics maintain that programs aimed at addressing community health goals use approaches that minimize—

not merely reduce—their infringement on individual autonomy, and that such interventions must be "necessary in degree as well as in kind."[27(p173)] Therefore, eliminating NMEs from all school-entry vaccines included in school immunization laws, despite these vaccines protecting against VPDs of varying threats to public health, warrants further deliberation.

Making Values Explicit

In addition to the need for an assessment of the range of possible outcomes that could follow NME elimination, we believe that policymakers who develop strategies to eliminate NMEs should make the values inherent to this policy transparent. Public health policymaking invariably requires the integration of evidence and values: policymakers must make subjective judgments, informed by often implicitly assumed values, about priorities and trade-offs, weighing risks and benefits on behalf of individuals and communities alike. These judgments—and the evidence and values that support them—should be deliberated upon openly in conversation with interested and affected professional and lay communities, including health care clinicians, public health professionals, and parents. Although these deliberations themselves can have unintended consequences (eg, they can be used by some to promulgate misinformation), they nonetheless help to protect against unexamined biases and overall foster a climate of openness and inclusion that ultimately promotes the development of sound policy and increases the likelihood of its acceptance.[28]

The full spectrum of value judgments embedded in policies and proposals to eliminate NMEs, however, has been relatively opaque thus far. For instance, implicit in the ongoing calls to eliminate NMEs is that the increased level of risk of VPD associated with allowing them is justification enough.[3] Although there has been an appropriate emphasis on the increased relative risk of developing and transmitting VPD by claiming an exemption (underscoring the benefit of vaccination), there has been less consideration given to the likely less than 1% absolute risk of developing a VPD,[5] even during epidemics.[29] Yet, there is substantial merit to debating and articulating both the degree of risk posed by unvaccinated children—in terms of magnitude and severity among individuals and communities—as well as community values related to what level of absolute risk warrants restricting individual choice by eliminating NMEs for a particular VPD (or for any VPD). A careful assessment of how such risk compares with other anticipated or foreseeable outcomes that might follow other exemption policy options could be instructive in determining whether the policy to eliminate NMEs represents the optimal strategy.

Conclusions

Proposed strategies to eliminate NMEs from school vaccination laws in the United States should stimulate renewed and ongoing discussion among policymakers, health care clinicians, public health practitioners, and the public about anticipated outcomes of eliminating NMEs and strategies to prevent or minimize unintended consequences. A deliberative and precautionary approach such as this can help to ensure that eliminating NMEs is the best strategy to achieve vaccination coverage goals and to "establish the conditions under which it can be successful."[30(p711)] As state legislatures around the country are actively debating whether to eliminate NMEs, the time for this discussion is now. We call for a neutral forum, such as a workshop hosted by the National Academies of Science, Engineering, and Medicine, to foster this dialogue.

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Author Affiliations: Treuman Katz Center for Pediatric Bioethics, Seattle Children's Research Institute, Seattle, Washington (Opel, Diekema); Department of Pediatrics, University of Washington School of Medicine, Seattle (Opel, Diekema, Marcuse); Department of Health Policy and Management, Yale School of Public Health, New Haven, Connecticut (Schwartz); Departments of Epidemiology and Global Health, Emory University School of Public Health, Atlanta, Georgia (Omer); Emory Vaccine Center, Atlanta, Georgia (Omer, Orenstein); Department of Health Policy and Management, Indiana University Fairbanks School of Public Health, Indianapolis (Silverman); Indiana University McKinney School of Law, Indianapolis (Silverman); Public Health-Seattle and King County, Seattle, Washington (Duchin); Department of Epidemiology, University of Washington School of Public Health, Seattle (Duchin); Department of Medicine, University of Washington School of Medicine, Seattle (Duchin); Pediatric Institute and Department of Bioethics, Cleveland Clinic, Cleveland, Ohio (Kodish); Department of Medicine, Emory University School of Medicine, Atlanta, Georgia (Orenstein).

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